In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 18-0559V UNPUBLISHED

WANDA RODGERS,

Petitioner.

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: March 11, 2020

Special Processing Unit (SPU); Findings of Fact; Site of Vaccination Tetanus Diphtheria acellular Pertussis (Tdap) Vaccine; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Isaiah Richard Kalinowski, Maglio Christopher & Toale, PA, Washington, DC, for petitioner.

Mallori Browne Openchowski, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT¹

On April 18, 2018, Wanda Rodgers filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq.² (the "Vaccine Act"). Petitioner alleges that she suffered shoulder injuries related to vaccine administration ("SIRVAs") in both right and left shoulders casually related to the influenza ("Flu") and tetanus, diphtheria, acellular pertussis ("Tdap") vaccinations which she received on September 13, 2016. Petition at ¶¶ 3, 14, 17. Petitioner maintains that the

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

vaccine record, which indicates she received both vaccinations in her left deltoid, is erroneous, and that in fact she received one vaccination in each arm. Petition at ¶ 3; see Exhibit 1 at 65 (vaccine record). The case was assigned to the Special Processing Unit of the Office of Special Masters.

For the reasons discussed below, I find Petitioner received one vaccination in her left deltoid, and the other vaccination in her right deltoid.

I. Relevant Procedural History

Shortly after filing her petition, Ms. Rodgers filed her medical records and a statement of completion. Exhibits 1-4 and Statement of Completion, filed Apr. 19, 2018, ECF Nos. 4-5. Following the initial status conference, she filed her affidavit. Exhibit 5, filed July 30, 2018, ECF No. 11.

On March 1, 2019, Respondent filed a status report indicating he believed additional medical records were outstanding -- specifically physical therapy ("PT") records and additional documentation regarding the sites of vaccination. ECF No. 19. On May 6, 2019, Petitioner filed her PT records and updated medical records from her orthopedist. Exhibits 6-7, ECF No. 21. Petitioner also filed a document titled "Objections" arguing that Respondent improperly included his request for additional documentation regarding the sites of vaccination in a status report and requesting that Respondent be required to file his Rule 4(c) report. ECF No. 22. A call was scheduled for May 23, 2019.

During the call, the parties discussed how best to handle the issue regarding the sites of vaccination in this case. Petitioner was allowed time to provide any additional evidence she could obtain regarding the administration of the vaccinations alleged as causal and to state her preference regarding the next step in the case. Order, issued May 24, 2019, ECF No. 23. In the order, it was noted that Respondent would be allowed to provide his preference thereafter. *Id.*

On August 8, 2019, Petitioner filed additional evidence, obtained from the vaccine administrator, Petitioner's primary care provider ("PCP") Dr. Katzen, regarding the general practice followed by personnel at the clinic when administering two vaccinations, the method by which vaccine records are created, documentation of calls Petitioner made to the clinic in October and November 2016, and a duplicate copy of the medical record for Petitioner's visit to the clinic on October 4, 2016. Exhibit 8, ECF No. 28. Thereafter, the staff attorney contacted the parties by email correspondence regarding their preferred next step. The parties agreed that Petitioner should file a motion, requesting a factual finding regarding the sites of vaccination. Order, issued Aug. 12, 2019, ECF No. 30.

On October 15, 2019, Petitioner filed her motion for a factual finding with a supporting memorandum attached. Motion for Finding of Fact Regarding Injection Site, ECF No 31; Petitioner's Memorandum of Law in Support of Petitioner's Motion for Finding

of Fact Regarding Injection Site, ECF 31-1. Approximately one month later, on November 14, 2019, Respondent filed his response. Respondent's Response to Petitioner's Motion for Ruling on the Record ("Res. Response"), ECF No. 33. On November 26, 2019, Petitioner filed a reply. Petitioner's Reply Memorandum in Support of Petitioner's Motion for Finding of Fact Regarding Injection Site, ECF No. 34.

II. Issue

At issue is whether the vaccines alleged as causal in this case were administered, one in each arm, as Petitioner alleges, or both in her left deltoid as indicated in the vaccine record. Both vaccines are covered by the Vaccine Program, and Petitioner alleges that she suffered SIRVAs in both shoulders. 42 C.F.R. § 100.3(a) I., II., XIV. (2017) (most recent Vaccine Table including the Flu and Tdap vaccines).

III. Authority

Pursuant to Vaccine Act § 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act § 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized, however, that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did

not exist. La Londe v. Sec'y of Health & Human Servs., 110 Fed. Cl. 184, 203-04 (2013), aff'd, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." § 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); see also Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make this finding after a complete review of the record to include all medical records, affidavits, testimony, expert reports, respondent's Rule 4 report, and additional evidence filed. Specifically, I base the finding on the following evidence:

- On September 13, 2016, at an appointment with her PCP, Petitioner received the Flu and Tdap vaccinations. Exhibit 1 at 65.
- On October 4, 2016, Petitioner called the clinic of her PCP (Dr. Katzen), where she received the vaccinations in question, complaining of soreness in both arms after receiving the Flu and Tdap vaccinations the prior month. Exhibit 8 at 2. Petitioner first spoke to an individual who reported Petitioner "still cannot bring her arm over her head without pain since her last vaccines 3 weeks ago." *Id.* The call was routed another individual at the clinic. After

speaking to Petitioner, this individual noted Petitioner "c/o^[3] soreness on both arms from when she got the Flu and Tdap vaccine on 9-13-16" and "can't sleep cause no matter which side she turns, her <u>arms</u> hurt." *Id.* (emphasis added). Petitioner's PCP indicated that he wished to see Petitioner. *Id.*

- At her appointment that same day, Petitioner repeated her complaint of pain in both arms after receiving the Flu and Tdap vaccinations on September 2016.⁴ Exhibit 1 at 2 (indicating "c/o both arms are very painful"). When examining Petitioner, Dr. Katzen observed that she had bilateral tautness and pain. Exhibit 1 at 3 (indicating "B/I^[5] deltoid taut and painful").
- Petitioner called her PCP three more times during the month on October 7, 13, and 27, 2016. Exhibit 8 at 8-12. The notes from the October 27, 2016 call indicate Petitioner wished "to speak with staff about her injection site^[6]" and that she had come "in for her flu and Tdap shot and then discovered pain in her shoulders after her injections were given." *Id.* at 8.
- When visiting her surgeon, Dr. Rivera, on November 8, 2016, Petitioner indicated she wished to postpone surgery on her right medial arm and right medial knee masses^[7] because she was having soreness from immunizations. Exhibit 2 at 12-13.
- Petitioner called her PCP again on November 10, 2016. Exhibit 8 at 7. On that call, Petitioner "stated her <u>arms/shoulder</u> pain is about the same, not better." *Id.* (emphasis added).
- At her initial visit with Dr. Campbell at Southwest Arthritis Research Group on February 1, 2017, Petitioner indicated that, after receiving the Flu and Tdap vaccinations in October or November, "she developed swelling in her lateral shoulders (near injection sites) and pain in her shoulders." Exhibit 3

³ The abbreviation "c/o" can stand for the phrase "complains of". MEDICAL ABBREVIATIONS at 141 (16th ed. 2020).

⁴ The exact date in this record is listed as September 16, 2016. Exhibit 1 at 2. However, as noted earlier in this ruling, the correct date of vaccination is September 13, 2016. Exhibit 1 at 65.

⁵ It appears this abbreviation stands for "bilateral". MEDICAL ABBREVIATIONS at 89 (indicating the abbreviation "BL" can mean bilateral).

⁶ Although this entry uses the singular site, instead of sites, it also references to two vaccination. Exhibit 8 at 8. Thus, it appears the use of the singular site was a simple mistake.

⁷ When she received the vaccinations alleged as causal in this case, Petitioner was visiting her PCP for follow-up regarding these two masses. Exhibit 1 at 62. At that visit, she indicated she had these lipomas for five years, that the lipoma on her knee was increasing in size and painful, and that the lipoma on her right arm hurt when she exercised. She requested this surgical referral at that visit. *Id.* A lipoma is "a benign, soft, rubbery, encapsulated tumor of adipose tissue, usually composed of mature fat cells." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ("DORLAND'S") at 1063 (32th ed. 2012).

at 7. She indicated she "was diagnosed with cellulitis and treated with bactrim." *Id.*

- When Petitioner was first seen by an orthopedist on April 5, 2017, she indicated "[s]he had vaccines in both shoulders back in September." Exhibit 4 at 5. She described her pain as immediate, present for six months. The orthopedist, Dr. Flanagin, opined that Petitioner's "[s]ymptoms seem consistent with SIRVA" and injected both shoulders with lidocaine and Kenalog. *Id.* at 7-8.
- At her initial PT appointment, Petitioner reported that both her shoulders became swollen after receiving the Flu and Tdap vaccinations. Exhibit 7 at 13, 17. This history is included in the medical records from each subsequent session. *Id.* at 20, 23, 26, 29, 32, 35, 38, 41, 47, 50, 53.
- Petitioner's PCP provided written responses to questions posed by Petitioner's counsel. According to these written responses, the clinic's policy is to administer vaccines in both shoulders when administering more than one vaccine. Exhibit 8 at 1. Furthermore, the vaccination administration site "is documented in an electronic health record, with a 'drop down' box, where the person administering the vaccination selects the administration location." Id.

The above medical entries show Petitioner consistently reported pain and/or soreness in both shoulders after receiving the Flu and Tdap vaccinations. Although Petitioner generally referred to the location of her symptoms, rather than the injections themselves, the inference that she received the vaccinations in both shoulders is clear. At her April 5, 2017 visit to her orthopedist, Petitioner specifically stated that the September vaccinations were administered in both shoulders. Exhibit 4 at 5. At a February 1, 2017 visit to Dr. Campbell she described her bilateral swelling as occurring "near site injections". Exhibit 3 at 7.

Petitioner made five of these representations within 60 days of vaccination, to individuals at her PCP's clinic where she received the vaccines. The documentation regarding these complaints contain no evidence that individuals at the clinic disagreed with or attempted to contradict Petitioner's representation that she received the vaccines alleged as causal in both shoulders. Furthermore, when seen by her PCP on October 4, 2016, 21 days after vaccination, he observed tautness and pain in both shoulders. Exhibit 1 at 3.

Respondent argues that the histories provided by Petitioner in the more contemporaneously created medical records should be given little weight since they are derived from information provided by Petitioner. Res. Response at 6. Respondent seems to argue these histories should be afforded the same weight as later allegations made by a petitioner in a vaccine proceeding. *Id.* (quoting § 13(a)(1) ("the special master . . . may not make such a finding . . . based on the claims of a petitioner alone, unsubstantiated by medical record or medical opinion"). However, the Federal Circuit has stated that "[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied to or by health professionals to facilitate diagnosis and

treatment of medical conditions." *Cucuras*, 993 F.2d at 1528 (emphasis added). Thus, the Circuit has instructed that greater weight should be accorded to this information even when the information is provided by Petitioner.

The record evidence, by contrast, is somewhat thinner in supporting administration having only occurred in one arm -- although the document that says so is the vaccine record itself. Exhibit 1 at 65. But Petitioner has offered persuasive arguments for why this record should not be taken at face value. As indicated in the documentation provided by Petitioner's PCP, in filing out a vaccine administration record, the administrator would note the site of vaccination in an electronic record, using a "drop down" box. This method of documentation requires less effort on the part of the administrator than other methods, such as a written notation or requirement to circle left or right deltoid. Given that Petitioner received two vaccinations that day, it is reasonable to infer that the administrator mistakenly clicked the "drop down" box for left deltoid both times. It is unlikely that the vaccine administrator or Petitioner would have noticed this type of mistake.

Additionally, Petitioner's PCP has noted the general practice at his clinic is to administer one vaccine in <u>each</u> arm. Exhibit 8 at 1. Although Petitioner was experiencing lipomas on her right arm and knee which had existed for five years, the location of the mass on her right arm should not have caused the vaccine administrator to deviate from this general practice. As noted in the medical records from Petitioner's surgeon, Dr. Rivera, the lipomas were located on the medial right arm and medial right knee. Medial means "pertaining to the middle; closer to the median plane or the midline of a body or structure." Dorland's at 1118. Thus, it appears Petitioner's lipomas were located lower on her arm, possibly on the inner part of her elbow and the inner side of her right knee. This placement would not have caused the vaccine administrator to avoid injecting Petitioner's right shoulder. In fact, the medical record from that September 13, 2016 visit indicates Petitioner's blood pressure was taken on her right arm. Exhibit 1 at 63. Additionally, it appears that Petitioner received an influenza vaccination in her right upper arm in October 2012, at a time when her lipomas were most likely present. Exhibit 1 at 90.

There is one other entry (from the record of Petitioner's October 4, 2016 call to her PCP) which would support the proposition that Petitioner received both vaccines in her left deltoid. This record is from the individual who first answered Petitioner's call, and indicates Petitioner purported that she could not raise her arm (singular) due to the vaccines she received. Exhibit 8 at 2. However, that entry is contradicted by the note from the individual to whom the call was transferred and history provided by Petitioner at the visit later that same day. Those entries clearly indicate Petitioner complained of soreness and pain in both shoulders. Exhibit 1 at 2; Exhibit 8 at 2, 4.

Accordingly, I find there is preponderant evidence to establish the two vaccinations alleged as causal in this case were administered on September 13, 2016, one in Petitioner's left deltoid and one in Petitioner's right deltoid.

V. Scheduling Order

Given my finding of fact regarding the site of Petitioner's vaccinations, Respondent should evaluate and provide his current position regarding the merits of Petitioner's case.

Respondent shall file a Status Report regarding his current position by no than <u>Friday</u>, <u>April 10</u>, <u>2020</u>.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master